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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/424,629	03/13/2000	SIMON FOOTE	13203	8264

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EXAMINER

MYERS, CARLA J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 04/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Interview Summary</b>	<b>Application No.</b> 09/424,629	<b>Applicant(s)</b> FOOTE ET AL	
	<b>Examiner</b> Carla Myers	<b>Art Unit</b> 1634	

All participants (applicant, applicant's representative, PTO personnel):

- (1) Carla Myers. (3) Frank DiGiglio.  
 (2) Xiaochun Zhu. (4) \_\_\_\_\_.

Date of Interview: 12 April 2005.

Type: a) ☒ Telephonic b) ☐ Video Conference  
 c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☐ No.  
 If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: all.

Identification of prior art discussed: Kamb, Koster, McCarthy.

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

  
 CARLA J. MYERS  
 PRIMARY EXAMINER

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

\_\_\_\_\_  
 Examiner's signature, if required

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

#### Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant's representative indicated that the claimed invention was distinguishable over the method of Kamb in that the claimed invention allowed for the detection of a mutation at an unknown location. Applicant's representative further noted that the claimed invention can be used to detect any sequence variation within a large sequence and thereby the position and identity of the sequence variation need not be known prior to performing the detection method. The examiner stated that an amendment to the claims to recite that the mutation to be detected was at an unknown location would not distinguish the claimed method over that of Kamb. Kamb is not viewed as teaching the detection of only mutations which occur at a specific known location. Rather, Kamb teaches that reagents such as T1 ribonuclease can be used for the digestion step. Since this nuclease does not cleave at only a site containing a particular mutation (as is the case with selected restriction enzymes), the analysis of the digestion products allows for the detection of both known and unknown mutations. Further, it is noted that Kamb (see abstract) states that the disclosed method is not limited to analyzing for mutations or polymorphisms in known genes associated with diseases, but rather the method may be used to screen candidate gene sequences for mutations in a positional cloning project or for genotyping. The examiner indicated that the specification does not define "mutations at unknown locations" in a manner which would distinguish the present invention over the method of Kamb and that the method of Kamb would necessarily allow for the detection of both known and unknown mutations. Applicant's representative stated that while the method of the present invention allows for the analysis of mutations in large nucleic acid fragments, Kamb teaches the analysis of shorter nucleic acid fragments. It was agreed that Kamb exemplifies methods in which PCR is performed to generate fragments of 40bp and mutations within the 40 bp fragment are detected. Kamb also teaches that when larger fragments are to be analyzed, the nucleic acid is further digested with restriction enzymes which cleave at known locations within the fragment to be analyzed. However, the present claims do not recite any limitations which distinguish the claimed method over the method of Kamb because the present claims do not recite a minimum length limitation for the size of the fragment that is to be digested and then subjected to MALDI-TOF MS analysis. Lastly, the examiner indicated that the arguments presented during the interview and in the previous response to the final office action are not applicable to the rejection over claims 10-18 and 34 as these claims relate to a computer program for controlling a method for detecting nucleotide variation. It was pointed out that the claimed computer program required only a means for controlling a method, but did not require performing the active process steps set forth in the method claims.